In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS
No. 21-1606V

TAYLOR WILLIAMS,	*	Chief Special Master Corcoran
Petitioner,	*	Filed: April 29, 2024
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Nancy R. Meyers, Turning Point Litigation, Greensboro, NC, for Petitioner.

Colleen C. Hartley, U.S. Department of Justice, Washington, DC, for Respondent.

RULING ON ENTITLEMENT[1]

On July 22, 2021, Taylor Williams filed this action seeking compensation under the National Vaccine Injury Compensation Program (the " Vaccine Program").[2] Petition (ECF No. 1). Petitioner alleges the Table claim that an influenza ("flu") vaccine she received on November 26, 2018, caused her to incur Guillain-Barré syndrome ("GBS"). *Id.*

I set a schedule for briefing on entitlement, and both sides have offered their position. *See* Petitioner's Motion for Ruling on the Record, dated Mar. 22, 2024 (ECF No. 41) ("Br."); Respondent's Brief, dated Apr. 19, 2024 (ECF No. 42) ("Opp."). Although Respondent contests

[1] Under Vaccine Rule 18(b), each party has fourteen (14) days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the whole Decision will be available to the public in its present form. *Id.*

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended at 42 U.S.C. §§ 300aa-10 through 34 (2012) [hereinafter "Vaccine Act" or "the Act"]. Individual section references hereafter will be to § 300aa of the Act (but will omit that statutory prefix).

entitlement (at least in terms of how he construes the record), he has represented that he will not defend against the entitlement phase of the claim. Opp. at 10; Amended Rule 4(c) Report, dated Jan. 30, 2024 (ECF No. 40) at 10. Based on the foregoing, as well as my own review of the record, I find that Petitioner has met the flu vaccine-GBS Table requirements, and therefore is entitled to damages.

I. Fact History

Vaccination and Evidence of Intercurrent Infection

On November 26, 2018, Ms. Taylor, then 15 years old, went to Nurse Practitioner Lynn Kitchel for a routine wellness visit. Ex. 1 at 74. At this time, she received the subject flu vaccine (as well as another vaccine not herein alleged as causal of injury). *Id*. at 79–80. A neurological exam then performed yielded normal results. *Id.*

Less than one month later, on December 21, 2018, Petitioner was treated by NP Kitchel for "URI symptoms." *Id.* at 87. She reported that her symptoms (body aches, chills, fever, nasal congestion, headache, and dizziness) had begun five days before. *Id*. Testing was performed to identify possible infectious etiologies for her symptoms (in particular, Influenza A and B, plus Epstein-Barr virus), but all produced negative results, and NP Kitchel diagnosed petitioner with an unidentified "[v]iral upper respiratory illness." *Id*. at 89. A few days later, Petitioner reported some improvement, albeit with nasal congestion, and her high temperature began to decline. Ex. 1 at 96, 99.

However, on December 24th, and after Petitioner's mother had spoken to NP Kitchel about observed symptoms improvements, Petitioner was taken to an urgent care facility, where she was seen by Nurse Practitioner Mendy Sharpe, complaining of "headache, nasal congestion, productive cough, fever, fatigue, and body aches that began 1 week ago." Ex. 10 at 15. NP Sharpe diagnosed her with acute bronchitis and prescribed an inhaler and antibiotic. *Id*. at 16.

Beginning of Neurologic Symptoms

On January 2, 2019—now 37 days after the subject vaccination—Ms. Taylor was taken to the WakeMed Raleigh emergency department. Ex. 2 at 768–70. She reported numbness in her legs and fingers over the past two days, and also informed treaters of her previously-diagnosed bronchitis and antibiotic course. *Id.* An exam revealed that Petitioner's lower extremity strength and reflexes were diminished, and it was recommended she obtain a neurologic consult. *Id.* at 772.

Petitioner was subsequently admitted to the hospital for further neurologic evaluation. *Id.* Spinal and brain MRIs initially performed were normal. *Id.* at 799. But a nerve conduction study demonstrated evidence of left tibial neuropathy with both axonal and demyelinating features. *Id*.

at 800. The treating neurologist proposed the overall picture was most consistent with GBS, although not definitively enough for the diagnosis, and Petitioner received a course of IVIG.[3] Ex. 2 at 814.

On January 8, 2019, Petitioner was discharged to an inpatient rehabilitation facility with the diagnosis of GBS (although because of the nature of her presentation, it was not deemed to fit the "classic" form). *Id.* at 798. By January 24, 2019, she had completed rehabilitation. *Id.* at 152–53. At the time of discharge, she was free of numbness or tingling in her lower extremities, and displayed moderate to full strength in bilateral lower extremities as well. *Id*. Indeed, by the end of that month, Petitioner was able to engage in school sports to a more limited extent, and her neurologic evaluation by NP Kitchel was deemed normal. Ex. 1 at 117. On January 28, 2019, after eight outpatient physical therapy ("PT") visits, Petitioner was deemed to have met her goals and discharged for home exercise. Ex. 3 at 11.

On March 20, 2019, Petitioner saw Dr. Traci Sheaffer, a pediatric neurologist. Ex. 4 at 2–5. She reported overall improvement, but did not feel that she had yet returned to full strength. *Id*. Her neurological examination was deemed normal, except for consistently absent deep tendon reflexes, and it was advised she continue to work with a personal trainer on her deficits while also following up for additional neurologic treatment in the future. *Id.*

Subsequent Treatment

For the remainder of 2019 to the present, Petitioner had additional treatment on several occasions, although most of her subsequent health issues cannot be reasonably linked to her earlier GBS diagnosis. In particular, the record reveals many instances in which Petitioner complained of headaches that she reported were possibly associated with a different vaccine she had received in the fall of 2018, although the neurologic exams she repeatedly received yielded normal findings. *See, e.g.*, Ex. 10 at 8–11 (May 2019 urgent care visit for headaches); Ex. 6 at 29–30 (October 2019 visit with primary care provider), 11 (February 2020 treater visit, complaining of fever and headache); Ex. 4 at 21.

Ms. Taylor did, however, have follow-up visits with neurologists for further evaluation and treatment of her post-GBS sequelae. *See, e.g.*, Ex. 4 at 7–10 (November 2019 visit with Dr. Sheaffer), 12–16 (February 2020 visit with Dr. Sheaffer). At some of these visits, there was discussion of whether headaches could reflect post-GBS sequelae, although other etiologic explanations were favored. Ex. 4 at 21 (April 2020 visit with Dr. Shaeffer; headaches attributable to orthostatic hypotension), 23 (May 2020 telemedicine visit with Dr. Sheaffer), 28 (June 2020

[3] "Intravenous immunoglobulin" is a blood product used to treat patients with antibody deficiencies, including neurological disorders. *Clinical Use of Intravenous Immunoglobulin*, NCBI (2005) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1809480/ (last visited on Apr. 29, 2024).

telemedicine visit with Dr. Sheaffer). By an October 2020 visit with Dr. Shaeffer, Petitioner was reporting that her headaches had improved, although she continued to experience some motor deficits thought to be GBS-related, and leading Dr. Sheafer to propose PT for strength building. *Id.* at 33–35.

II. Treater Statement

While this action was pending, in September 2023 Petitioner submitted in support of her claim, an unsworn letter from Dr. Sheaffer. *See generally* Ex. 11. In it, Dr. Sheaffer concludes that Petitioner "suffered Guillain-Barre Syndrome ("GBS") following vaccinations." *Id*. at 1. She also acknowledges that Petitioner "had an intercurrent upper respiratory infection[] in mid-December and bronchitis in later December but had been feeling better prior to her second immunization." *Id.* Dr. Sheaffer concludes that "the immunizations were more likely than not to be a substantial factor in causing her GBS," and that her treatment of Petitioner later included headaches and dizziness (although other than their post-GBS character, makes no statements as to their relationship). *Id.*

III. Procedural History

The case was initiated in July 2021, and (after the process for evaluating the sufficiency of document filings in the case was completed), assigned to the "Special Processing Unit" in April 2022, based on the initial supposition that the Table claim alleged was amenable to settlement. Thereafter, however, despite some efforts to settle the matter, the parties proved unable to come to an agreement, and the case was subsequently transferred to my own docket in October 2023. I ordered Respondent to file an expert report or some other evidence supporting the "factor unrelated" defense, since it appeared Petitioner could otherwise meet the elements of a flu vaccine-GBS Table claim. *See* Nov. 3, 2023 Scheduling Order. The parties filed the briefs referenced above, and the matter is now ripe for resolution.

IV. Parties' Arguments

Petitioner argues that she has met her *prima facie* burden of demonstrating a Table Injury—she received a flu vaccine, experienced GBS, and her onset fell within three to 42 days of vaccination. Br. at 7. She references the January 2019 clinical evidence of GBS-like symptoms (diminished reflexes, bilateral limb weakness, a monophasic injury course, and timeframe from onset to nadir consistent with the Table GBS definition). *Id.* at 8–10. She also asserts that there is no other evidence of an alternative cause (ignoring the proof of an intercurrent infection, but stressing Respondent's failure to preponderantly establish a counter-explanation). *Id.* at 10–11, 12.

Respondent's recitation of the fact history makes mention on several occasions of the intercurrent infection that Petitioner was clearly experiencing prior to formal onset of neurologic

symptoms in January 2019. Opp. at 2–3. Although Petitioner was diagnosed at this time with bronchitis, testing for infections in December yielded negative results. *Id.* Respondent also highlights that Petitioner's clinical presentation was not deemed consistent with GBS in a "classic sense," even though it was still thought to be GBS. *Id.* at 4. Otherwise, Respondent has reiterated that he will not defend against this claim (while reserving his right to argue in a damages phase that certain claimed costs or expenses are not injury-related). *Id.* at 10.

V. Applicable Legal Standards

A. *Petitioner's Overall Burden in Vaccine Program Cases*

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a "Table Injury"—i.e., an injury falling within the Vaccine Injury Table—corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).[4] In this case, Petitioner asserts the Table claim of GBS caused by the flu vaccine.

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Hum. Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Hum. Servs*., 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

[4] Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Hum. Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Hum. Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd* 104 F. Appx. 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Hum. Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

B. *Legal Standards Governing Factual Determinations*

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [ ] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Hum. Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (determining that it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

As noted by the Federal Circuit, "[m]edical records, in general, warrant consideration as trustworthy evidence." *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Hum. Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd*, *Rickett v. Sec'y of Health & Hum. Servs*., 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). A series of linked propositions explains why such records deserve some weight: (i) sick people visit medical professionals; (ii) sick people attempt to honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 11–685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Hum. Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs*., No. 03–1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are often found to be deserving of greater evidentiary weight than oral testimony—especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Hum. Servs*., 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. den'd*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary

weight.")).

However, the Federal Circuit has also noted that there is no formal "presumption" that records are accurate or superior on their face to other forms of evidence. *Kirby v. Sec'y of Health & Hum. Servs.,* 997 F.3d 1378, 1383 (Fed. Cir. 2021). There are certainly situations in which compelling oral or written testimony (provided in the form of an affidavit or declaration) may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Hum. Servs*., 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Hum. Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Hum. Servs*., No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs*., 110 Fed. Cl. 184, 203–04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. *Standards for Ruling on the Record*

The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers where (in the exercise of their discretion) they conclude that doing so will properly and fairly resolve the case. Section 12(d)(2)(D); Vaccine Rule 8(d). The decision to rule on the record in lieu of hearing has been affirmed on appeal. *Kreizenbeck v. Sec'y of Health & Hum. Servs*., 945 F.3d 1362, 1366 (Fed. Cir. 2020); *see also Hooker v. Sec'y of Health & Hum. Servs*., No. 02-472V, 2016 WL 3456435, at *21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided case on the papers in lieu of hearing and that

decision was upheld). I am simply not required to hold a hearing in every matter, no matter the preferences of the parties. *Hovey v. Sec'y of Health & Hum. Servs*., 38 Fed. Cl. 397, 402–03 (1997) (determining that special master acted within his discretion in denying evidentiary hearing); *Burns*, 3 F.3d at 417; *Murphy v. Sec'y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 71500, at *2 (Fed. Cl. Spec. Mstr. Apr. 19, 1991).

ANALYSIS

GBS is listed as a Table injury for the flu vaccine, and thus a claimant seeking to meet its requirements need not establish vaccine causation. Instead, Petitioner herein must show (a) receipt of a covered form of the flu vaccine, (b) that she did in fact experience GBS, as defined in the Table's "qualifications and aids to interpretation," and (c) that her symptoms onset (whether or not GBS could then be diagnosed, or in fact was) occurred between three and 42 days after vaccination. 42 C.F.R. § 100.3.

Here, there is no dispute that Petitioner received a version of the flu vaccine covered by the Program, and likely experienced GBS, with onset occurring within the Table-defined timeframe. Accordingly, she has met her *prima facie* case.[5]

At the same time, there is obvious unrebutted evidence that Petitioner experienced an intercurrent, if unidentified, infection far closer in time to onset of her GBS than vaccination. Certainly, these kinds of factual circumstances raise the possibility of a "factor unrelated" explanation for the injury—a showing that Respondent is burdened with establishing, when (as here) the burden of proof shifts after a claimant's *prima facie* success. Section 13(a)(1)(B); *Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1338 (Fed. Cir. 2010); *see also Schilling v. Sec'y of Health & Hum. Servs.*, No. 16-527V, 2022 WL 1101597, at *21 (Fed. Cl. Spec. Mstr. Mar. 17, 2022). I have dismissed flu vaccine-GBS Table claims where Respondent carried this burden, and in so doing explained how a closer-in-time infectious process can rule out vaccine causality—even though the Table presumes causation otherwise. *White v. Sec'y of Health & Hum. Servs.*, No. 20-1319V, 2023 WL 4204568, at *18 (Fed. Cl. Spec. Mstr. June 2, 2023), *mot. for review den'd*, 168 Fed. Cl. 660 (2023), *appeal docketed,* No. 2024-1372 (Fed. Cir. Jan. 23, 2024).

But in this case, I cannot find that burden-shifted showing has been made. Of course, Respondent has expressly opted *not* to attempt to make out the showing at all, and by abandoning that possibility it would almost be improper to conduct a factor unrelated analysis. But even despite

[5] As this is a Table claim, I do not (in assessing Petitioner's *prima facie* showing) analyze the confounding evidence of an alternative explanation that would often occur were this a causation-in-fact claim (an in particular, the "did cause" prong of that analysis). Causation is presumed under the circumstances, and therefore the obvious record evidence of alternative explanations for the injury are better evaluated as part of Respondent's "factor unrelated" burden. And of course, claimants are *never* obligated to *negate* the possibility that something else caused their injury—even though evidence of alternative causal factors often undermines a claimant's overall showing.

the presence of *some* evidence of an alternative explanation, I cannot find on this record that preponderantly some other infection was causal, ruling out vaccination. Testing for an alternative infection was inconclusive, and there has not been shown to be substantial treater support for an infection as causal (while there is treater support going the other way). All that remains is Petitioner's preponderant satisfaction of the Table elements.

CONCLUSION

Based on the entire record in this case, I find that Petitioner has provided preponderant evidence satisfying all requirements for a Table-GBS claim. Petitioner is thus entitled to compensation. I shall contact the parties shortly after issuance of this Ruling to hold a status conference about damages.

IT IS SO ORDERED.

/s/ Brian H. Corcoran
Brian H. Corcoran
Chief Special Master